AF/SGE-C Animal Use Appendix for Research Involving Animals
FULL VERSION

*****NOTE: SGE-C will ONLY review protocols that have been approved by your IACUC.*****
*******Animal work MAY NOT be initiated until the awardee receives SGE-C approval.*******
*******Animal work initiated before receipt of SGE-C approval will not be funded.*******

DoD-funded institutions using animals in U.S. Air Force sponsored research, product development, testing and education projects must provide electronic copies of the following documents to their DoD program manager for Air Force Surgeon General, Office of Research Oversight and Compliance (AF/SGE-C) review and approval:

a. a copy of their **IACUC-approved protocol(s)** (SGE-C will ONLY review **approved** protocols)
b. a copy of all IACUC-approved protocol amendments or modifications
(**major** changes must be reviewed and approved by SGE-C **PRIOR** to implementation)
c. a copy of this completed Appendix and associated documents for each IACUC-approved protocol.

This requirement also applies to all subcontractors using animals in support of U.S. Air Force sponsored DoD-funded projects or programs.

The DoD policies and requirements for the use of animals in DoD-funded research, development, testing and evaluation are described in DoD Instruction 3216.01, dated 13 Sept 2010 and Air Force Manual 40-401, *The Care and Use of Laboratory Animals in DOD Programs*, dated February 16, 2005. These requirements may differ from those of other funding agencies. Specific information requested in the following animal use Appendix is derived from requirements in the Animal Welfare Regulations (AWRs), the *Guide for the Care and Use of Laboratory Animals*, and other applicable Federal regulations and DoD directives. Use of the Appendix is intended to meet the requirements of these documents.

Questions concerning animal use and review should be directed to HAF/SGE-C:

Phone: 703-681-8160
Fax: 703-681-8050
Email: Robin L.Burke8.mil@mail.mil
Mail: Office of Research Oversight and Compliance
Office of the Air Force Surgeon General
ATTN: LTC Robin L. Burke
7700 Arlington Blvd Ste 5151
Rm# 3NW408A
Falls Church, VA 22042-5151

~~~~~~

Each section of this Appendix must be completed. Begin typing responses after the colon (":") for each section to ensure your typing is not within the hidden text. It is important that you carefully **read the instructions** for each paragraph to ensure you provide a comprehensive response. The additional instructions and written explanations provided for individual paragraphs are red, *italicized*, and coded as hidden text. To view the instructions and/or examples for each section, select the "**Show/Hide ¶**" button on your tool bar (the button itself appears as the ¶ symbol). To print the hidden text, select "Print" on the drop down file menu. Under the "Options" button, select "Hidden text" under the "Include with document" section. Please do not submit copies with the hidden text printed out to SGE-C.

Any section of the Appendix that is not applicable to your proposal, e.g., no surgery or no prolonged restraint, should be marked "**N/A**". There are no space limitations for the responses.

It is essential that only animal studies or procedures documented in an IACUC–approved protocol or amendment to the protocol be performed at your facility. Additionally, Principal Investigators or other delegated research personnel should keep accurate records and be able to provide an audit trail of all animal use that correlates to their approved protocol. SGE-C will collect this information for end-of-year DoD animal use reports.
~~~~~~

Before completing this Appendix, please ensure you can view the red, *italicized* hidden text that provides specific instructions for sections of this document.
Refer to the cover page for directions on viewing the hidden text in this document.
WHEN COMPLETING THIS APPENDIX, INCLUDE ONLY ANIMALS, EXPERIMENTS AND PROCEDURES THAT ARE FUNDED BY THIS GRANT/CONTRACT

1. Administrative Data: (Provide Attending Vet, IACUC, and Research Office info for the research site.)

DoD Grant/ContractPI Name: _____

Grant/Contract PI Email: _____ **Phone:** _____

Animal Research Site (RS): _____

Protocol PI Name: _____

Protocol PI Email: _____ **Phone:** _____

RS Attending Veterinarian: _____

RS Attending Vet Email: _____ **Phone:** _____

RS IACUC Office Point of Contact (POC): _____

RS IACUC POC Email: _____ **Phone:** _____

RS Grants Office POC: _____

RS Grants Office POC Email: _____ **Phone:** _____

Animal Protocol Title: _____

Brief Objective Summary:

2. Rationale for Using Animals:

3. Species Identification and Rationale:

a. Species:

b. Stock/Strain/Breed/Etc.:

c. Animal Model Rationale:

4. Experimental Design:

5. Specific Procedures / Technical Methods: In the subparagraphs listed below, provide a complete description of all procedures the animals will experience. Procedures not specifically addressed in subparagraphs a. through m. below should be described under Other Procedures (subparagraph n).

a. Animal Observations and Health Status Assessment Criteria:

b. Anesthesia/Analgesia/Tranquilization and /or Non-pharmaceutical Methods of Relieving Pain or Distress:

☐ Yes ☐ No Anesthetics/Analgesics/Tranquilizers will be used to relieve pain or distress.
☐ Yes ☐ No Non-pharmaceutical methods will be used to relieve pain or distress.

If "Yes" to either of the above,

i. Describe methods or strategies planned to effectively relieve pain and/or distress:

ii. Intraprocedural Observations: list the observational or monitoring criteria used to assess depth of anesthesia while the procedure is being performed and/or to determine if animals are experiencing pain or distress and require additional anesthetics, analgesics, tranquilizers or non-pharmaceutical pain relief:

c. Anesthesia/Analgesia/Tranquilization for Chemical Restraint:

☐ Yes ☐ No Anesthetics/Analgesics/Tranquilizers will be used for chemical restraint.

If "Yes,"

i. Describe methods or strategies planned for chemical restraint (i.e., if a procedure would not otherwise cause more than slight or momentary pain or distress, but the anesthetic is used to facilitate administration by holding the animal still):

ii. Intraprocedural Observations: list the observational or monitoring criteria used to assess depth of anesthesia while the procedure is being performed:

d. Paralytic Agents (Note: the use of paralytic agents without anesthesia is prohibited):

☐ Yes ☐ No Paralytic agents will be used during this protocol.

If "Yes," describe the following:

i. Rationale for using paralytic agents:

ii. Paralytic Agent Protocol (e.g., drug, dose, frequency of injection, etc.):

iii. Monitoring methods to ensure adequate depth of anesthesia while animal is under influence of paralytic agents:

e. Surgery:

☐ Yes ☐ No Surgical procedures are performed on live animals during this protocol.

If "Yes," describe the following:

i. Pre-operative Considerations and Animal Preparation:

ii. Surgical Procedures:

iii. Immediate and Long-Term Post-operative Monitoring/Observations/Treatment:

f. Multiple Major Survival Surgeries (performed on the same animal):

☐ Yes ☐ No Multiple major survival surgeries will be performed on the same animal.

If "Yes," provide a scientifically valid justification:

g. Biosamples:

☐ Yes ☐ No Biosamples are collected from animals during this protocol.

If "Yes," state the frequency, volume, harvest site, and collection method for each sample type (samples collected after euthanasia need not be described here but should be mentioned in section 4. Experimental Design above):

h. Adjuvants:

☐ Yes ☐ No Adjuvants are used in animals during this protocol.

If "Yes," list any adjuvants used and the plan for their use:

i. Genotyping/DNA Analysis:

☐ Yes ☐ No Genotyping/DNA analysis will be performed on animals during this protocol.

If "Yes," describe any methods used for genotyping or other DNA analysis:

j. Injections:

☐ Yes ☐ No Substances will be administered to animals by injection during this protocol.

If "Yes," at a minimum, describe the agent, dose, and route of administration for each type of injection and each compound/substance injected (injectable anesthetic or analgesic use should be described in 5.b. above and need not be repeated here):

k. Other Test Article or Therapeutic Agent Administration:

☐ Yes ☐ No Test articles, therapeutic agents, special diets or other compounds will be administered to animals by a route other than injection.

If "Yes," at a minimum, describe the agent or drug, dose, route and/or method of administration, frequency of administration, and duration of administration for each test article, therapeutic agent or other compound administered:

l. Prolonged Restraint:

☐ Yes ☐ No Animals will undergo prolonged restraint (as defined by institutional IACUC policies or the Animal Welfare Act regulations) during this protocol.

If "Yes," justify and describe restraint and duration in detail:

m. Behavioral Studies or Behavioral Modification Techniques:

☐ Yes ☐ No Animals will be involved in behavioral studies or undergo behavioral modification during this protocol.

If "Yes," describe any behavioral studies or modification planned for this protocol. Include details on the use of aversive stimuli and food and/or water regulation and/or restriction; describe other behavioral studies or methods of behavioral modification; describe the outcome or behavioral measures assessed and criteria used to evaluate the animal's performance; describe methods used to monitor physiological or behavioral indices, including criteria (e.g., % weight loss, hydration status, etc.) for temporary or permanent removal from the study:

n. Other Procedures (e.g., electrocardiograms, radiology or other imaging procedures, tissue perfusions, stress induction, etc.):

6. Rationale for Number of Animals Required/Animal Numbers/USDA Pain or Distress Category:

a. Statistical/Other Basis for Number of Animals Used:

b. Total Number of Animals Used (by Species) and USDA Pain/Distress Category :

SPECIES	HIGHEST USDA PAIN/DISTRESS CATEGORY (B, C, D, E*) See table below	TOTAL NUMBER

	for definitions	

USDA Pain/Distress Category Definitions:

- ***Column B:*** *Animals being bred, and animals being held for use in research, testing, teaching, experiments or surgery but not yet used for those purposes.*
- ***Column C:*** *List the number of animals that will experience no more than slight or momentary pain or distress as a result of experimental manipulations or procedures on this protocol.*
- ***Column D:*** *List the number of animals that will potentially experience more than momentary or slight pain or distress that* ***WILL*** *be alleviated through the use of anesthetics and/or analgesics.*
- ***Column E:*** *List the number of animals that will experience more than momentary or slight pain or distress that* ***WILL NOT*** *be alleviated or relieved with anesthetics or analgesics.* **If any animals are listed in USDA Column E (Unalleviated Pain or Distress), the PI must provide a scientifically valid justification for withholding pain relieving medication:**.

c. Column E only- If any animals are listed in USDA Column E (Unalleviated Pain or Distress), the PI must provide a scientifically valid justification for withholding pain relieving medication:

7. Columns D or E only- Consideration of Alternatives to Painful Procedures. If there are no animals listed in USDA Column D or E, mark this section "N/A." If **any animals are listed in USDA Column D or E**, the PI must perform this literature search. **You MUST provide a narrative summary of the results of the literature search for alternatives to painful procedures.** The Animal Welfare Act regulations specifically state that the P.I. must provide a narrative description of the methods and sources that he/she used to determine that alternatives to the painful or distressful procedure(s), including those in which pain or distress is alleviated, were not available: **DOD regulations require this for all animals undergoing painful procedures including those not covered by the Animal Welfare Act.**

8. Study Endpoint:

9. Euthanasia:

10. Literature Search for Unnecessary Duplication: This search is required for all animal use proposals. Note the DoD-specific database requirements in subparagraph a.

a. Indicate Literature Source(s) Searched:

http://www.ntis.gov/products/fedrip.aspxhttp://projectreporter.nih.gov/reporter.cfm

REQUIRED:

☐ Biomedical Research Database (BRD) http://brd.dtic.mil/

AT LEAST 1 REQUIRED:

☐ Federal Research in Progress (FEDRIP) -OR- http://www.ntis.gov/products/fedrip.aspx

☐ Research Portfolio Online Reporting Tool Expenditures and Results (RePORTER) http://projectreporter.nih.gov/reporter.cfm

b. Date of Search:

c. Years Covered by Search:

d. Key Words and/or Search Strategy Used:

e. Results of Search:

11. Qualifications:

STUDY PERSONNEL QUALIFICATIONS/TRAINING

Protocol activity or procedure (e.g., tail vein injections, euthanasia)	Name of person performing activity	Qualifications or experience of person performing activity in the proposed species (e.g., research technician; 2 yrs experience with intracranial surgical procedure; performed IP injections on 100s of mice)	**Specific** training in this activity or procedure (e.g., rodent handling class; trained to do surgical procedure by PI; aseptic surgical techniques training; rabbit intubation)

****Questions 12-18 refer to the Research Site and Protocol PI.****

Information and/or documents required in questions 12-16 should be obtained from the research site's IACUC or veterinary staff. Documents may be provided directly to SGE-C by the Protocol PI or institution staffs. If the Protocol PI prefers that SGE-C staff contact the institution to obtain this information and/or documents, the PI must specifically request this action in writing. The Protocol PI should send this written request via email to krinon.d.moccia.mil@mail.mil.

12. Institutional Animal Care and Use Committee(s) (IACUC) Approval(s):

Institutional Animal Use Protocol Number: _____

IACUC (initial) approval date: _____ Protocol expiration (rewrite) date: _____

13. Institutional Accreditation / Assurances:

a. Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) Accreditation:

☐ Yes ☐ No Animal work is being performed at an AAALAC International-accredited facility.

b. Public Health Service Animal Welfare Assurance Statement:

☐ Yes ☐ No Animal work is being performed at a PHS-assured facility.

c. Non-accredited, Unassured Facilities: If neither 13.a. nor 13.b. above apply to the facility where animal work is being performed, submit a statement signed by the Institutional Official that states

the care and use of animals will be conducted in accordance with the National Research Council's 2010 *Guide for the Care and Use of Laboratory Animals* and applicable Federal and DoD regulations.

14. Animal Procurement:

☐ Yes ☐ No If the protocol involves Animal Welfare Act-regulated species, are the animals obtained legally from suppliers licensed by the USDA? If the supplier claims exemption from USDA licensing, provide confirmation from the research site's IACUC that the exemption criteria have been met. If work is conducted outside the US, have animals been obtained legally in accordance with national policy? If wildlife are used, provide IACUC assurance that animals have been obtained legally and provide copies of applicable state and federal capture and use permits.

15. Veterinary Care Plan: Provide a brief description of the veterinary care plan at the research site. Describe routine care; weekend, holiday, and emergency care; and identify whether the attending veterinarian is on staff full-time or by contract.

16. Overseas / Foreign Country Animal Work:

☐ Yes ☐ No Animal work will be performed outside the United States.

If "Yes," answer the following questions.

a. What is the law or regulation governing the use of animals in research in the research site's host country? Please provide a copy or link to this law or regulation in English.

b. Does the research site's host country adhere to European Union (EU) Directive 86/609 or EU Directive 2010/63 standards of animal housing and care?

c. If the research site is in Canada, does the institution hold a Canadian Council on Animal Care (CCAC) certificate?

d. Does the research site adhere to any national or international standards of animal housing and care that are more stringent than the host country's laws or regulations (such as AAALAC or CCAC)? If so, please describe below or provide a document, in English, that describes these standards.

e. Does the research site's host country or local institute require a local ethical committee review or Animal Care and Use Committee review? If so, please describe below or provide a document, in English, describing the committee's membership, purpose, authority and function.

18. Site Visits

☐ Yes ☐ No Does animal work involve at least one of the following species: dogs, cats, nonhuman primates, marine mammals? If yes, provide a planned start date for work in these species and point of contact for site visit coordination. Based on accreditation status, species used, and type of research conducted, a site visit to the performance site may be required.

19. **Protocol Principal Investigator Assurances:**

The law specifically requires several written assurances from the P.I. Please read and sign the assurances as indicated (this page may be photocopied and signed).

As the Principal Investigator on this protocol, I acknowledge my responsibilities and provide assurances for the following:

A. Painful Procedures: I assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research and that analgesic, anesthetic, and/or tranquilizing drugs will be used where indicated and appropriate to minimize pain and/or distress to animals.

B. Animal Use: The animals authorized for use in this protocol will be used only in the activities and in the manner described herein, unless a modification is specifically approved by the IACUC and the U.S. Air Force Surgeon General's Office of Research Oversight & Compliance (SGE-C) prior to its implementation.

C. Duplication of Effort: I have made a reasonable, good faith effort to ensure that this protocol is not an unnecessary duplication of previous experiments.

D. Statistical Assurance: I assure that I have consulted with a qualified individual who evaluated the experimental design with respect to the statistical analysis, and that the minimum number of animals needed for scientific validity will be used.

E. Training: I verify that the personnel performing the animal procedures/manipulations/observations described in this protocol are technically competent and have been properly trained to ensure that no unnecessary pain or distress will be caused to the animals as a result of the procedures/manipulations.

F. Responsibility: I acknowledge the inherent moral, ethical and administrative obligations associated with the performance of this animal use protocol, and I assure that all individuals associated with this project will demonstrate a concern for the health, comfort, welfare, and well-being of the research animals. Additionally, I pledge to implement animal use alternatives where feasible, and conduct humane and lawful research.

G. Scientific Review: This proposed animal use protocol has received appropriate peer scientific review, and is consistent with good scientific research practice.

_____ _____

(Protocol Principal Investigator Printed Name) (Protocol Principal Investigator Signature and Date)

NOTE: In accordance with AFMAN 40-401_IP, the SGE-C (or designee thereof) will conduct a site visit to all sites using nonhuman primates, dogs, cats or marine mammals in the proposal, or where a site visit is deemed warranted.